

REMARKS

Claim Status

Claims 1-10 and 14-30 are pending in the present application. No additional claims fee is believed to be due.

Claims 11-13 were previously canceled without prejudice.

Claims 1, 6, 8 and 9 are amended herein. Support for the amendment is found in the specification at, *inter alia*, page 12, lines 26-29.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 U.S.C. §101

In Paragraph 3 of the Office Action dated 12/09/08, Claims 9, 10, 14-20, 25-26 and 30 stand rejected under 35 U.S.C. §101 based on the Office's assertion that these method claims do not recite a device which is used for carrying out the method. Applicant respectfully traverses the rejection.

Claim 9 recites "a method for improving the health of an individual including the steps of: . . . e. analyzing . . . data *via at least one data analysis mechanism* to define at least one of an out-of-control situation requiring intervention and potential causes or remedies of an out-of-control situation wherein the data analysis mechanism performs at least one analysis based on the historical or recent health data of the individual, selected from the group consisting of: statistical control chart techniques, multi-variate analysis, attribute data analysis, and reliability engineering analysis [emphasis added]" By dependency, Claims 10, 14-20, 25-26 and 30 include these elements.

Thus, these claims do recite a device which is used for carrying out the method. Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection.

Rejections Under 35 U.S.C. §103(a)

Under MPEP §2142, the Office bears the burden of factually supporting an asserted *prima facie* conclusion of obviousness. In determining the differences between the cited art and the claims, the question is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *See, e.g., Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1537; 218 U.S.P.Q. 871 (Fed. Cir. 1983). If the Office does not demonstrate *prima facie* unpatentability, then without more, the Applicant is entitled to the grant of the patent. *See In re Oetiker*, 977 F.2d 1443, 1445; 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992).

To establish a *prima facie* case of obviousness under 35 U.S.C. §103, the Office must show that all of the claim elements are taught or suggested in the prior art. *See, e.g., CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342; 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003).

Rejection of Claims 1, 2, 5, 9, 10, 14-20 and 25-30 Over Sheehan in view of Frasca, Jr. in further view of Walker and in even further view of Filangeri

In Paragraph 5 of the Office Action, Claims 1, 2, 5, 9, 10 and 14-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sheehan (USPN 6,319,199) in view of Frasca, Jr. (USPN 6,055,506) in even further view of Walker (USPN 5,828,751) and in even further view of Filangeri (USPN 6,093,146). In Paragraph 5(D), Claims 25 and 26 stand rejected over the same references. In Paragraph 5(E), Claims 26-30 stand rejected over the same references and Official Notice.

Applicants respectfully traverse the rejection.

Without conceding the correctness of the rejection in any respect, and without waiving any other arguments they may have, Applicants discuss only particular elements below.

As amended, Claim 1 recites a system to improve the management of an individual's health, the system including, *inter alia*, at least one data analysis mechanism that performs at least one analysis based on historical or recent health data of the

individual collected in accordance with a sampling strategy comprising collection of the data on a plurality of days. By dependency, Claims 2 and 5 include these elements.

As amended, Claim 9 recites a method for improving the health of an individual including the steps of, *inter alia*, creating a sampling strategy comprising collection of data on a plurality of days, for measuring at least one health parameter of interest. By dependency, Claims 10, 14-20 and 25-30 include these elements.

With respect to Claims 1 and 9, and the claims that depend from them, the Office concedes that the combination of Sheehan, Frasca, Jr. and Walker does not teach analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy (Office Action, Page 4), or creating a sampling strategy (Office Action, Page 6). The Office contends that these missing elements are taught by Filangeri.

As defined by Applicants, “‘sampling strategy’ refers to the choice(s) or plan for the frequency and timing and method for data measurement.” (Specification, page 12, lines 16-17.) Applicants respectfully submit that Filangeri does not teach a sampling strategy. Rather, as best understood by Applicants, Filangeri only teaches a device that has the capability to collect data samples at a rate (100 samples/second) and store 88 minutes of patient data. There is no mention or suggestion of a sampling strategy involving choice(s) or a plan.

Additionally, there is no mention or suggestion in Filangeri of a sampling strategy comprising collection of data on a plurality of days, as recited by amended Claims 1 and 9.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 6, 7 and 23 over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri and in even further view of Litt and in even further view of Filangeri

In Paragraph 6 of the Office Action, Claims 6, 7 and 23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sheehan (USPN 6,319,199) in view of Frasca,

Jr. (USPN 6,055,506) in view of Walker (USPN 5,828,751) in view of Filangeri (USPN 6,093,146) in view of Litt (USPN 6,658,287) and in even further view of Filangeri. Applicants respectfully traverse the rejection.

Without conceding the correctness of the rejection in any respect, and without waiving any other arguments they may have, Applicants discuss particular elements below.

As amended, Claim 6 recites a system to improve the management of an individual's health, the system including, *inter alia*, at least one data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy comprising collection of the data on a plurality of days. By dependency, Claims 7 and 23 include these elements.

The Office concedes that the combination of Sheehan, Frasca, Jr., Walker and Litt does not teach analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy (Office Action, Page 9). The Office contends that these missing elements are taught by Filangeri.

As defined by Applicants, "sampling strategy" refers to the choice(s) or plan for the frequency and timing and method for data measurement." (Specification, page 12, lines 16-17.) Applicants respectfully submit that Filangeri does not teach a sampling strategy. Rather, as best understood by Applicants, Filangeri only teaches a device that has the capability to collect data samples at a rate (100 samples/second) and store 88 minutes of patient data. There is no mention or suggestion of a sampling strategy involving choice(s) or a plan.

Additionally, there is no mention or suggestion in Filangeri of a sampling strategy comprising collection of data on a plurality of days, as recited by amended Claim 6.

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of Claims 8 and 24 over Sheehan in view of Frasca, Jr. in view of Walker in view of Filangeri in further view of Falcone and in even further view of Zadrozny

In Paragraph 7 of the Office Action, Claims 8 and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sheehan (USPN 6,319,199) in view of Frasca, Jr. (USPN 6,055,506) in view of Walker (USPN 5,828,751) in view of Filangeri (USPN 6,093,146) in further view of Falcone (USPN 5,464,102) and in even further view of Zadrozny (USPN 6,540,674). Applicants respectfully traverse the rejection.

Without conceding the correctness of the rejection in any respect, and without waiving any other arguments they may have, Applicants discuss particular elements below.

As amended, Claim 8 recites a system to improve the management of an individual's health, the system including, *inter alia*, at least one data analysis mechanism that performs at least one analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy comprising collection of the data on a plurality of days. By dependency, Claim 24 includes these elements.

The Office concedes that the combination of Sheehan, Frasca, Jr., Walker, Falcone and Zadrozny does not teach analysis based on historical or recent health data of the individual collected in accordance with a sampling strategy (Office Action, Page 12). The Office contends that these missing elements are taught by Filangeri.

As defined by Applicants, “sampling strategy” refers to the choice(s) or plan for the frequency and timing and method for data measurement.” (Specification, page 12, lines 16-17.) Applicants respectfully submit that Filangeri does not teach a sampling strategy. Rather, as best understood by Applicants, Filangeri only teaches a device that has the capability to collect data samples at a rate (100 samples/second) and store 88 minutes of patient data. There is no mention or suggestion of a sampling strategy involving choice(s) or a plan.

Additionally, there is no mention or suggestion in Filangeri of a sampling strategy comprising collection of data on a plurality of days, as recited by amended Claim 8.

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For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Remaining Statutory Rejection

The remaining statutory rejection set forth in the Office Action in Paragraph 9 thereof concerns only dependent Claim 4. Claim 4 is dependent from Claim 1. As set forth above, Applicants submit that Claim 1 is patentable over the art of record. If Claim 1 is patentable, then Claim 4, being dependent therefrom and narrower in scope, is also patentable. Applicants, therefore, without conceding the correctness of the rejection or waiving any arguments they may have, defer argument concerning Claim 4 and the rejection set forth in the Office Action at Paragraph 9 thereof.

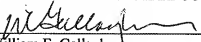
Conclusion

This response represents an earnest effort to place the present application in proper form for allowance. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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